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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,826	02/08/2002	Mitchell F. Brin	17326CIP2 (BOT)	2841

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,826	BRIN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-15,18-20 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,34 and 35* is/are allowed.

6)☒ Claim(s) *1,4,6,8-10, 12-15,18-20,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/16/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2006 has been entered.

2. Claims 1, 4, 6, 8-15, 18-20 and 32-35 are pending.

Claim 12 has been amended.

Claims 34 and 35 have been added.

Claims 1, 4, 6, 8-15, 18-20 and 32-35 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 103

3. The rejection of claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (Movement Disorders 13(1): 188-190, January 1998/ IDS reference CB submitted June 16, 2003) is withdrawn in light of Applicants' amendment to claim 12 and corresponding arguments.

Maintained Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 1, 4, 6, 8-10, 12-15, 18-20, 32 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a mammary gland disorder with *Clostridial neurotoxin botulinum* toxin A and *Clostridial difficile* toxin A, does not reasonably provide enablement for treating a mammary gland disorder with any Clostridial neurotoxin or preventing development of a mammary gland neoplasm/carcinoma is maintained.

Applicants assert, it's well known that botulinum toxin types B-G can substitute for type A and consequently the claims are fully enabled. Applicants' also assert Schantz et al. (1992, submitted November 23, 2005) substantiates Applicants' assertion and further notes the different types of botulinum toxin may be used to "complement" or "substitute" botulinum toxin type A for treating a condition, see page 7 of Remarks submitted September 25, 2006. Applicants quote the article but do not point out where the citation can be found. Notwithstanding, the arguments, Schantz and Applicants' points of view have been carefully considered, but found unpersuasive.

Foremost, some of Applicants' claims continue to include methods for preventing development of a mammary gland neoplasm/ carcinoma, see claims 15, 20 and 32. The specification fails to provide sufficient guidance to enable one of ordinary skill in the

art to practice the claimed method in a manner reasonably correlated with the intended use of prevention. While technologies exist in which one of skill in the art can implement diagnostic assays in order to determine risk factors and assess whether or not the likelihood or propensity exists to determine if one may incur a disease, the ability to prevent disorders, diseases and particularly mammary gland cancers is limited. At best early detection and effective treatments for breast cancer have significantly improved, however the possibility of breast cancer recurrence is an ongoing concern and the possibility of prevention is inadequate, see bridging paragraph of pages 193 and 194 and Cancer Prevention section on page 198 of Herbst et al. (Journal of Clinical Oncology 24(1): 190-205, January 1, 2006). Even in 2006 cancer prevention is still at the research level and not at the level of assured predictability. There are no reasons why one of skill in the art would expect the claimed method would be capable of preventing a mammary disorder including breast cancer given the unpredictable nature of treating cancer. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to implement a method for preventing the development of mammary cancer. Without such guidance the specification does not support the treatment of any breast cancer/carcinoma/neoplasm in the realm of prevention. None of the examples presented in the specification supports that at the time of the claimed invention was made that Applicants were able to prevent or protect against any type of cancer. There is no guidance in the specification as to how to determine and select a population of individuals, which may or may not eventually have cancer. It is not clear

what parameters one skilled in the art would use in order to identify a population of subjects that cancer could be prevented.

Applicants quote Schantz within their Remarks on page 7, first full paragraph stating "...types other than type A will be used clinically,..." and "evidence is accumulating to show that different types bind to different acceptors and may have subtle differences in their mode of action and that **they could therefore complement type A in clinical applications.**" This citation is not sufficient in overcoming the enablement rejection because these are prophetic and speculative statements and there is no corresponding evidence. Also "complementing" type A in clinical applications is not the same thing as actually "substituting" or using in lieu of type A. Complementing suggests one of ordinary skill in the art could implement one of types B-G as an accompaniment or with type A and this is not provided for in Schantz or the specification and nor is Applicants' suggestion of substituting the use of one of types B-G instead of type A. Neither, Schantz nor the specification provides any scientific evidence that substantiates the feasibility of administering any one of types B-G, in lieu of type A.

The Examiner has set forth in the first action on the merits (FAOM) mailed October 14, 2005 the unpredictability of treating cancer and the differences between the toxin types. The treatment of specific mammary diseases with *C. botulinum* type A and *C. difficile* toxin A neurotoxins cannot be extrapolated to the treatment of all mammary diseases with all the toxin types. Thus, one of skill in the art could not practice the

broadly claimed method, of treating and preventing a mammary gland disorder with all botulinum toxin types with a reasonable expectation of success.

Allowable Subject Matter

6. Claims 11, 34 and 35 allowed.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
8 December 2006